

Workshop overall programme

Workshop 2 - PREPARATION PROCESS AUTHORISATION

5, 6, 7 June 2024

Tutors and External experts involved:

S. Pupella, J. Kurz, R. Barrio, S. Masterson, U. La Rocca, A. Vassanelli, A. Kurzreiter, R. Piteira (Euro-GTP Expert), DG SANTE, P. Versura (CNS Expert), G. Ianiro (CNT Expert)

Learning objectives:

- To understand the approach concerning the SoHO preparation process authorisation system, joint SoHO preparation assessments, authorisation of imported/exported SoHO;
- To further familiarize with the GAPP guideline application, including the assessment of clinical efficacy as a part of PPA of innovative SoHO products/processes;
- To highlight what is new in the SoHO Regulation and the interaction with medical devices and ATMP regulations as well as Regulation and Directive of medicinal products and their impact on inspections and authorisation processes.

Agenda

Day 0. Tuesday 04/06/2024

| Time | Session | Title |
|---------------|----------|-----------------------------------|
| 14:00 - 17:00 | Briefing | Briefing session for Facilitators |

Day 1. Wednesday 5/06/2024

| Time | Session | Title | Tutor/s - Expert/s |
|--------------|---------|---|--|
| 8:30 - 9:00 | | Registration | |
| 9:00 - 9:15 | | Welcome message | (Training Coordinator - S. Pupella, DG SANTE, HaDEA - A. Binder) |
| 9:15 - 9:45 | | Brief Introduction (overview of related eLearning modules contents outcomes and take-home messages) and Workshop 2 expectations and scope | R. Barrio |
| 9:45 - 11:00 | Topic 1 | Ongoing EU Legal Provisions towards the new forthcoming Regulation | |
| 9:45 - 10:10 | | Frontal lecture- (CAs obligations, conditional authorisation) | DG SANTE |



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| 10:10 - 10:30 | | Frontal lecture Bridging SoHO BTCs to Medical Devices & ATMPs & their Competent Authorities | J. Kurz |
| 10:30 - 11:00 | | Plenary discussion with facilitators | S. Pupella, J. Kurz, R. Barrio, S. Masterson, U. La Rocca, A. Vassanelli, Observers: DG SANTE |
| 11:00 - 11:15 | | Coffee break | |
| 11:15 - 13:00 | Topic 2 | Preparation Process Dossier | |
| 11:15 - 11:40 | Exercise 1 | Brief intro on the PPD and presentation of cases study (substantial change control assessment) | R. Barrio A. Vassanelli J. Kurz S. Masterson S. Pupella U. La Rocca R. Barrio |
| 11:40 - 13:00 | | Working groups (4) on substantial changes applied in different processes harmonising the approach <ul style="list-style-type: none"> - Introduction of a new serological test without CE mark (WC1 and WC2) - Introduction of a substantial change in the storage procedure (WC3 and WC4) | A. Vassanelli R. Barrio J. Kurz S. Masterson S. Pupella U. La Rocca Observers: DG SANTE |
| 13:00 - 14:00 | | Lunch break | |
| 14:00 - 15:15 | | Working group rapporteurs' presentation, plenary discussion and take-home messages | R. Barrio |
| 15:15 - 16:45 | Topic 3 | Role of the assessors | |
| 15:15 - 15:45 | | Frontal lecture on the role of assessors, how the inspector may play the role of assessor too (training, inspector curriculum) | J. Kurz A. Kurzreiter |
| 15:45 - 16:00 | | Coffee break | |
| 16:00 - 16:30 | | Plenary discussion and take-home messages | S. Pupella - J. Kurz |
| 16:30 - 16:45 | | Recap of the day and closing remarks | J. Kurz |
| 19.30 | | Social dinner at Gusto restaurant Piazza di Sant'Apollinare, 41, 00186 Rome | |



Day 2. Thursday 06/06/2024

| Time | Session | Title | |
|--------------|-------------------|---|---|
| 8:30 - 9:00 | | Registration | |
| 9:00 - 12:00 | Topic 4 | Euro-GTP II risk assessment tool application | |
| 9:00 - 9:20 | | Brief overview of Euro-GTP tool contents given in the dedicated eLearning module and brief intro to future development | R. Piteira (EuroGTP expert) |
| 9:20 - 9:40 | Exercise 2 | Presentation of cases study: 1. Descemet's Membrane Endothelial Keratoplasty (DMEK) 2. Introduction of a new donor hemoglobin testing | 1. S. Masterson/R. Barrio 2. S. Pupella/U. La Rocca |
| 9:40 - 10:00 | | Coffee Break | |
| 10:00-10:40 | | Discussion in working groups | 1. S. Masterson 2. R. Barrio, A. Vassanelli 3. S. Pupella 4. J. Kurz, U. La Rocca |
| 10:40-11:45 | | Cases study to be assessed and discussed in plenary | S. Pupella, J. Kurz, R. Barrio, S. Masterson, U. La Rocca, A. Vassanelli Observers: R. Piteira, DG SANTE |
| 11:45-12:00 | | Preliminary take-home messages | R. Piteira (EuroGTP expert) |
| 12:00-17:00 | Topic 5 | Novelties: scientific state-of-the-art (the expert point of view), preparation process authorisation (CA approach) | |
| 12:00-12:30 | | Lecture on faecal microbiota (scientific background, consolidated application, future development) | G. Ianaro (CNT) |
| 12:30-13:00 | | Q&A and plenary discussion | |
| 13:00-14:00 | | Lunch break | |
| 14:00-14:30 | | Lecture on serum eye drop (scientific background, consolidated application, future development) | P. Versura (CNS) |
| 14:30-15:00 | | Q&A and plenary discussion | |
| 15:00-15:20 | | Coffee break | |
| 15:20-16:00 | | GAPP methodology | R. Barrio - S. Pupella |
| 16:00-16:30 | | Q&A and plenary discussion | |



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| 16:30-16:45 | | Recap of the day and closing remarks | R. Barrio |
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Day 3. Friday 07/06/2024

| Time | Session | Title | |
|---------------|-------------------|---|------------------------|
| 8:30 - 9:00 | | Registration | |
| 09:00 - 10:00 | | Final Examination (Multiple choice) | |
| 10:00 - 10:15 | | Coffee break | |
| 10:15 - 13:00 | Topic 6 | Assessing/inspecting products and processes | |
| 10:15 - 10:40 | | Frontal lecture on critical process parameters and the critical product attributes. | S. Masterson |
| 10:40 - 11:00 | | Plenary discussion | |
| 11:00 - 11:15 | Exercise 3 | Introduction and indications for Role play | J. Kurz - S. Masterson |
| 11:15 - 12:30 | | Role play | |
| 12:30 - 13:00 | | Plenary discussion on Role play outcomes | |
| 13:00 - 14:00 | | Lunch break | |
| 14:00 - 15:30 | Topic 7 | EU ongoing initiatives | |
| 14:00 - 14:20 | | Frontal lecture on EGALiTE | R. Piteira |
| 14:20 - 14:40 | | Frontal lecture on GAPP-PRO | CNS-CNT |
| 14:40 - 15:00 | | Plenary discussion | |
| 15:00 - 15:30 | | Recap of the day and closing remarks | |



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